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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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272 7590 07/31/2009 SCULLY, SCOTT, MURPHY & PRESSER, P.C. 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530				
EXAMINER				
GOON, SCARLETT Y				
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1623				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,692

Applicant(s)

EROMA ET AL.

Examiner

SCARLETT GOON

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009 and 21 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-73 and 75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-73 and 75 is/are rejected.
- 7) ☒ Claim(s) 58 and 75 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 February 2009 has been entered.

This Office Action is in response to Applicants' Amendment and Remarks filed on 25 February 2009 in which claims 1-57 and 74 were cancelled, claim 58 is amended to change the scope and breadth of the claim, and new claim 75 is added.

Claims 58-73 and 75 are pending in the instant application and are examined on its merits herein.

Priority

This application is a National Stage entry of PCT/FI03/00533 filed on 2 July 2003 and claims priority to foreign application Finland 20021312 filed on 3 July 2002. A certified copy of the foreign priority document in Finnish is received.

Objections Withdrawn

In view of the cancellation of claim 48, all objections made with respect to claim 48 in the previous Office Action are withdrawn.

These objections have been **withdrawn**.

Rejections Withdrawn

In view of the cancellation of claims 38-57 and 74, all rejections made with respect to claims 38-57 and 74 in the previous Office Action are withdrawn.

These rejections have been **withdrawn**.

Claim Objections

Claims 58 and 75 are objected to because of the following informalities:

The preposition "of" should be inserted before "5-10 micrometers in size" and "0.05%-0.5%" in step (c) of claims 58 and 75 in order to render the claims grammatically correct.

The conjunction "and" should be inserted after "micrometers in size" to render the claim more grammatically correct.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-73 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of step (d) in claims 58 and 75 wherein the composition of step (c) is milled to a mean particle size of 0.1 – 0.4 mm after step (c) which requires that the microcrystallized particles obtained after conditioning are 5 – 10 μm in size, renders the claims herein indefinite. It is unclear what Applicants are intending to claim since the final milled particle size in step (d) is larger than the particle size prior to milling.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 58-60, 62-73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,764,706 B1 to Heikkilä *et al.* (herein referred to as the '706 patent, of record), in view of US Patent No. 5,017,400 to Olinger *et al.* (herein referred to as the '400 patent, of record).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The Heikkilä '706 patent teaches a process for the crystallization of xylitol (claim 1), comprising the steps of (a) spraying an aqueous solution of xylitol, that is present at a concentration between 30% - 80% by weight, into contact with gas suspended fine solid particles containing microcrystalline xylitol, (b) causing substantial removal of the water solvent from said aqueous solution in the gas suspended state, and (c) causing said xylitol composition to be conditioned during a further drying step to provide a product consisting of microcrystals of xylitol agglomerated together in a random manner. In addition to microcrystalline xylitol, other sweeteners that are preferably non-cariogenic may be added to the xylitol composition (column 3, lines 40-45). The processed crystalline xylitol can be made into confectionery, foodstuffs, pharmaceuticals, and oral hygiene products (section 1, lines 6 and 35 and claim 18).

To obtain a solid feed of said fine solid particles containing microcrystalline xylitol, the Heikkilä '706 patent teaches that a portion of the microcrystalline xylitol particles, having a desired mean particle size below 0.2 mm (equivalent to 200 μm) are

further recirculated (claim 17). In the absence of microcrystalline xylitol, the solid feed used at the start-up of the process may comprise milled crystalline xylitol from another source (column 2, line 62). Additionally, in example 3 of the reference, it is shown that powdered xylitol can also be used as the solid feed during start-up (column 8, line 57). The Heikkilä '706 patent further indicates that the suitable ratio of liquid xylitol feed to solid xylitol feed varies with the microcrystallization conditions (column 5, line 25), and can therefore be adjusted accordingly. Table 1 disclose conditions wherein the DS concentration of the feed solution is 65.6% or 72% (columns 7 and 8). Additionally, the crystal mass may also include minor portions of amorphous xylitol (column 3, lines 22-23).

For the process involving water solvent removal, the Heikkilä '706 patent further stipulates that the process provides a xylitol material dried to a free moisture content of about 0.1% – 3% while said xylitol material is still in a suspended state (claim 6). Furthermore, the solid particles are to be retained in a fluidized state until they have grown to a predetermined weight (claim 16). The xylitol material is then collected by allowing it to settle on a moving belt and to form thereon a substantially continuous agglomerated porous powder layer (claim 8).

For the conditioning step in the process for crystallization of xylitol, the Heikkilä '706 patent indicates that the microcrystallized particles are conditioned at a temperature of about 50 °C - 100 °C (claim 9). Thereafter, the microcrystalline xylitol particles are broken up and further fractionated (equivalent to sieving) so as to provide particles having a mean particle size of about 0.1 – 10 mm (claims 12-14), preferably

about 0.15 – 0.4 mm (column 6, line 23). However, the reference teaches that xylitol particle size is not critical, and may be varied according to intended use of the product (column 3, line 12).

The Heikkilä '706 patent also teaches that microcrystalline xylitol may be microcrystallized with other compounds (column 3, line 63). If the solid and/or liquid feed comprises other components, the product discharged from the microcrystallization apparatus will contain said other component(s) (column 3, line 65). These components can be an excipient, an active ingredient, and/or other sweetener (claim 3). Such other sweeteners are preferably also non-cariogenic (column 3, lines 44-45). An alternate process by which other components can be microcrystallized with xylitol is by using a secondary spray containing the excipient, active ingredient, or sweetener (column 4, line 1 and claim 4).

It is noted that the Heikkilä '706 patent does not explicitly teach that the microcrystals obtained after conditioning is 5-10 μm in size with a free moisture content of 0.05% - 0.5%, as instantly claimed. With regards to the free moisture content, as the Heikkilä '706 patent teaches that xylitol is dried to a free moisture content of about 0.1% – 3%, prior to conditioning, it is considered that after performing the subsequent conditioning step at a temperature of about 50 °C - 100 °C the free moisture content cannot be higher than what it started out being as no additional solvent has been introduced to the material, and the heat during the conditioning step will only naturally evaporate away more solvent. With regards to the size of the microcrystals, it is believed that Applicants intended to indicate 5-10 mm in size. In this regard, the

selected particle size of microcrystals is obvious since it is not a patentable modification in the absence of unobvious results. See *In re Rose*, 105 USPQ 237. Furthermore, the size of the crystals obtained after conditioning is not deemed to be critical as the final size of microcrystals disclosed in the Heikkilä '706 patent after milling, 0.15 – 0.4 mm, is the same as that instantly claimed.

It is further noted that although the Heikkilä '706 patent teaches that microcrystalline xylitol may be microcrystallized with other compounds by discharging a solution containing both the xylitol and the other compound, or by using a secondary spray containing the other compound, separate from xylitol, the Heikkilä '706 patent does not explicitly indicate whether the separate solutions are sprayed simultaneously or intermittently onto the dry feed particles. However, as both methods would yield a similar result, it is considered within the capabilities of one of ordinary skill in the art to determine the method most suitable for their intended purpose.

Although the Heikkilä '706 patent teaches that other components, such as non-cariogenic sweeteners, may be microcrystallized with microcrystalline xylitol, the Heikkilä '706 patent does not explicitly teach a process for the microcrystallization of polyols wherein the polyols comprise at least two polyols.

The Olinger '400 patent teaches a sweetener composition which contains, as its principal ingredients, from about 10% - 90% by weight of crystalline maltitol and from about 90% - 10% by weight of crystalline xylitol. Xylitol is the sweetest sugar-free alcohol and is considered isosweet to sucrose (column 1, line 38). Maltitol has a sweetness similar to that of sucrose, a sweetness equivalent to 0.8-0.9 of sucrose

(column 2, line 8). Their comparable sweetness to sucrose makes these polyols ideal as sucrose replacements. Furthermore, a xylitol and maltitol combination exhibits sweetness synergism that also lacks the undesired burning aftertaste of pure xylitol (abstract; claim 1). The maltitol/xylitol sweetener composition is used to sweeten sugar-free products such as chocolate and other confectionery products, as well as dietetic products (column 1, line 9). Olinger *et al.* also teach that this sweetener composition is noncariogenic and, in some instances, cariostatic (column 1, line 12).

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the Heikkilä '706 patent, regarding a process for the microcrystallization of xylitol with other components, with the teachings of Olinger *et al.*, which teaches a sweetener composition that contains a combination of maltitol and xylitol. One would have been motivated to combine the teachings in order to receive the expected benefit, as suggested by Olinger *et al.*, that a combination of xylitol and maltitol exhibits sweetness synergism, and also lacks the undesired burning taste of pure xylitol. Since the Heikkilä '706 patent teaches that other sweeteners that are preferably non-cariogenic may also be added to the xylitol composition for microcrystallization, one of ordinary skill in the art would have reasonably expected the addition of maltitol to the xylitol microcrystallization process to result in co-crystallization of maltitol and xylitol. With regards to the limitation wherein each of the dissolved polyols must be present in at least 25% by weight, it is noted that the Heikkilä '706 patent only teaches that the xylitol purity is preferably more than 80%. Furthermore, with regards to the limitations of claim 71 wherein the conditioned temperature is about

67-70 °C and the limitations of claim 75 wherein the conditioned temperature is 65-72 °C, it is noted that the Heikkilä '706 patent only teaches a temperature in the range of 50-100 °C. However, it would have been *prima facie* obvious for one of ordinary skill in the art to vary the different concentration and temperature conditions of the method so as to obtain an optimal method for producing a product with optimal taste. See below for recitation of a section from MPEP § 2144.05 regarding the obviousness of optimization of ranges.

The following is a quotation of MPEP § 2144.05:

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 25 February 2009 with respect to the rejection of claims 38-60 and 62-74 made under 35 USC § 103(a) as being unpatentable over WIPO publication WO 91/07100 to Oravainen *et al.*, in view of U.S. Patent No.

6,764,706 B1 to Heikkilä *et al.*, in view of U.S. Patent No. 5,017,400 to Olinger *et al.*, have been fully considered but they are not persuasive. Applicants are requested to note that the rejection has been modified, as indicated above, such that the claims are unpatentable over U.S. Patent No. 6,764,706 B1 to Heikkilä *et al.*, in view of U.S. Patent No. 5,017,400 to Olinger *et al.*

Applicants argue that maltitol, xylitol and lactitol all require very high purity of their aqueous solutions for satisfactory conventional crystallization and that at the time of the present invention, it was not known how to satisfactorily crystallize the individual polyols from aqueous solutions containing impurities, such as other polyols in amounts as high as 25%. To substantiate their argument, Applicants indicate that the prior art only includes documents describing the crystallization of polyols on their own. These arguments are found not persuasive because the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See also MPEP § 2145 [R-6] regarding the consideration of Applicant's rebuttal arguments.

The following is a quotation of MPEP § 2145:

A showing of unexpected results must be based on evidence, not argument or speculation. *In re Mayne*, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997) (conclusory statements that claimed

compound possesses unusually low immune response or unexpected biological activity that is unsupported by comparative data held insufficient to overcome prima facie case of obviousness).
Rebuttal evidence may include evidence of the state of the art, the level of skill in the art, and the beliefs of those skilled in the art. See, e.g., *In re Oelrich*, 579 F.2d 86, 91-92, 198 USPQ 210, 214 (CCPA 1978) (Expert opinions regarding the level of skill in the art were probative of the Nonobviousness of the claimed invention.)

Furthermore, in order to prove the claimed subject matter solved a problem that was long standing in the art there must be a showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there must be evidence showing that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

The Applicants further argue that the Heikkilä '706 patent teaches that the purity of the xylitol should be more than 80%, and therefore teaches away from the present invention. Additionally, Applicants argue that it is more than routine experimentation since the disclosed product of the Heikkilä '706 patent does not include polyols in addition to xylitol. These arguments are not persuasive because the Heikkilä '706 patent teaches that the xylitol purity of the product is preferably more than 80% indicating that it can be lower than 80%. Furthermore, since the Heikkilä '706 patent specifically teaches that other non-cariogenic sweeteners can be added to the microcrystalline xylitol (column 3, lines 44-45), one of ordinary skill in the art would have been motivated to optimize the 80/20 amount of xylitol and other polyol in the composition so as to achieve a composition with ideal taste. Moreover, contrary to Applicants argument that the prior art only discloses the crystallization of polyols on their own and not in a composition, Applicants are requested to note that U.S. Patent

No. 5,958,471 to Schwarz *et al.* disclose a mixed polyol composition comprising 70:29:1 of sorbitol/xylitol/mannitol obtained by co-spray drying (column 2, lines 16-20).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

SCARLETT GOON
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